October 13, 2021

Ultradent Products, Inc.
Adam Black
Regulatory Affairs Manager
505 West Ultradent Drive (10200 South)
South Jordan, Utah 84095

Re: K211905
Trade/Device Name: UltraCal XS
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF, EJK
Dated: July 15, 2021
Received: July 16, 2021

Dear Adam Black:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211905

Device Name
UltraCal XS

Indications for Use *(Describe)*
UltraCal XS calcium hydroxide paste is indicated to be used for:
• temporary dressing for root canals
• apexification and/or perforation
• vital pulpotomy
• direct pulp capping
• indirect pulp capping
• root resorption
• root canal filling for primary teeth

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary-K211905

This summary of the traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 for UltraCal XS.

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Mr. Adam Black
Title:	Regulatory Affairs Manager
Telephone:	801-553-4425
Cell Phone:	435-459-9302
Fax:	801-553-4609

Date Summary Prepared: 22 September 2021

II. Name of the Device

Device:	Resin, Root Canal Filling
Trade/Device Name:	UltraCal XS
Common Name:	Root Canal Filling Resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3820
Device Class:	Class II
Classification Product Code:	KIF
Subsequent Product Code:	EJK

III. Device Description

UltraCal XS calcium hydroxide paste is an aqueous, 12.0 to 12.5 pH, radiopaque, premixed paste for direct application.

IV. Statement of Intended Use

UltraCal XS calcium hydroxide paste is indicated to be used for:

- Temporary dressing for root canals
- Apexification and/or perforation

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- Vital Pulpotomy
- Direct Pulp Capping
- Indirect Pulp Capping
- Root resorption
- Root canal filling for primary teeth

V. Predicate Device

UltraCal XS identified primary predicate: DiaPaste (K210333); secondary predicates: CleaniCal (K201799), TheraCal DC (K180344), Dia-Root Bio MTA (K200174).

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of UltraCal XS are substantially equivalent to the identified predicate as outlined in Table 5-1:

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Table 5-1: UltraCal XS substantial equivalence comparison

Descriptive Information/ characteristic	Primary Predicate: DiaPaste (K210333)	Device: UltraCal XS	Secondary Predicate: CleaniCal (K201799)	Secondary Predicate: TheraCal DC (K180344)	Secondary Predicate: Dia-Root Bio MTA (K200174)	Differences
Product Code	KIF	KIF, EJK	EJK, KIF	EJK	KIF	Similar
Intended Use	Aqueous ointment material that temporarily fills the root canal for the following indications: -Apexification -Temporary root filling -Root canal filling for primary teeth -Vital pulpotomy -Temporary pulp capping	UltraCal XS calcium hydroxide paste is indicated to be used for: •Temporary dressing for root canals •Apexification and/or perforation •Vital Pulpotomy •Direct Pulp Capping •Indirect Pulp Capping •Root resorption •Root canal filling for primary teeth	CleaniCal is a Calcium Hydroxide paste that has a creamy consistency and is suitable for several indications including. -Temporary disinfectant dressings in the obturation of root canals -Indirect pulp capping or management of deep caries lesions; or -Direct pulp capping	1. Pulpotomy 2. Temporary Filling Material 3. Repair of Root Perforations 4. Repair of Furcation Perforations 5. Repair of Perforating Internal and External Resorptions 6. Root-End Filling in Endodontic Surgery 7. Pulp Exposures (Direct Pulp Capping) 8. Protective Liner (Indirect Pulp Capping) and Base for Use Under a Variety of Substrates	DIA-ROOT BIO MTA is used for pulp capping (direct pulp capping or partial pulpotomy) and repair of root perforation. Other indications for use include: repair of root resorption, root end filling, apexification and pulpotomy.	Similar The Indications for Use of the subject device is within that of the predicate and reference device(s).
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Dental Professional	Dental Professional	Dental Professional	Identical
Characteristics	Calcium hydroxide paste with barium sulfate, used as a	Aqueous 12.0 to 12.5 pH calcium hydroxide, radiopaque, premixed	Pre-filled syringe with calcium hydroxide paste with a pH of 12.3.	TheraCal DC is a biocompatible, basic, dual-cured, resin-		Similar The subject device as well as the predicate

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Descriptive Information/ characteristic	Primary Predicate: DiaPaste (K210333)	Device: UltraCal XS	Secondary Predicate: CleaniCal (K201799)	Secondary Predicate: TheraCal DC (K180344)	Secondary Predicate: Dia-Root Bio MTA (K200174)	Differences
	temporary root canal filling material.	paste for direct application.		modified calcium silicate provided in a pre-filled syringe		and reference device(s) are both calcium hydroxide paste with relatively high pH.
Composition	-Calcium Hydroxide -Titanium Dioxide -Zinc Oxide -Barium Sulfate -Water -Polyether Polyol -Polysorbate (Tween80)	-Calcium hydroxide -Water -Barium Sulfate -Propylene Glycol -Hydroxypropyl Methylcellulose	-Calcium hydroxide -Zirconium dioxide - Excipients (nMethyl-2-pyrrolidone, Hypromellose)	-Calcium hydroxide -Portland Cement -All other components are proprietary	-Calcium silicate -Zirconium dioxide -Citric Acid -Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl-,hydrolysis products with silica -Hydroxypropyl methylcellulose	Similar The primary ingredient is equivalent in the predicate and subject device, calcium hydroxide. Barium sulfate is included in both as a radio-opacifier. Differences in the ingredients included varying chemicals used as thickeners, humectants, emulsifiers, etc. Dia-Root Bio MTA does not include calcium hydroxide as a component, however the hydration reaction during setting occurs between tricalcium

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Descriptive Information/ characteristic	Primary Predicate: DiaPaste (K210333)	Device: UltraCal XS	Secondary Predicate: CleaniCal (K201799)	Secondary Predicate: TheraCal DC (K180344)	Secondary Predicate: Dia-Root Bio MTA (K200174)	Differences
						silicate (3CaO·SiO2) and dicalcium silicate (2CaO·SiO2) to form a calcium hydroxide and calcium silicate hydrate gel, producing an alkaline pH.
Delivery System or Deployment Methods	Product is provided in a 2g syringe with disposable delivery tips	Product is provided in a 1.2mL syringe with disposable delivery tips	Pre-loaded syringe	Pre-loaded syringe	Powder within a cap & body to be mixed with distilled water on a mixing pad and applied intraorally with a spatula	Similar Both the subject device and the predicate and reference devices are provided in a pre-filled syringe with or without delivery tips. The difference with Dia-Root Bio MTA delivery is based on the necessary reaction with water to achieve performance.

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Descriptive Information/ characteristic	Primary Predicate: DiaPaste (K210333)	Device: UltraCal XS	Secondary Predicate: CleaniCal (K201799)	Secondary Predicate: TheraCal DC (K180344)	Secondary Predicate: Dia-Root Bio MTA (K200174)	Differences
Physical Properties	Confirmed to ISO 6876 -Flowability -Film Thickness -Radio-opacity	-Viscosity -Water Removal -Radio-Opacity	Confirmed to ISO 6876 -Packaging -Extraneous matter -Flowability -Radio-opacity	Confirmed to ISO 6876 -Radiopaque -Calcium releasing -Basic -Water sorption -Solubility	Confirmed to ISO 6876 -Setting time -Solubility -Radiopacity	Similar ISO 6876 is applicable for root canal sealing material, as UltraCal XS is not intended to seal root canals and was therefore deemed not applicable. Similar testing was performed to evaluate the characteristics of the chemistry.
Calcium Hydroxide Concentration	22-26%	35%	30%	Not specified	Not specified – based on ratio of distilled water and calcium silicate used	Similar Concentration range is within ranges cleared by FDA and does not raise new questions regarding safety and efficacy.
Patient Population	Individuals of all ages and gender and shall be assessed by the administering dental professional.	Individuals of all ages and gender and shall be assessed by the administering dental professional.	Individuals of all ages and gender and shall be assessed by the administering dental professional.	Not specified	Not specified	Identical

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Descriptive Information/ characteristic	Primary Predicate: DiaPaste (K210333)	Device: UltraCal XS	Secondary Predicate: CleaniCal (K201799)	Secondary Predicate: TheraCal DC (K180344)	Secondary Predicate: Dia-Root Bio MTA (K200174)	Differences
Biocompatibility and Safety	ISO 10993	ISO 7405:2018	ISO 10993	ISO 7405:2008 ISO 10993-1:2009	ISO 7405:2018	ISO 7405 was applied as it is a recommended biocompatibility evaluation standard for this product type.

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VII Conclusion:

The purpose of this submission was to address the change in indications for use of the previously submitted UltraCal XS (K970114). As outlined in the comparison table above, UltraCal XS is similar to the identified predicate device with respect to its intended use, its Intended User, the Device Design, Types of Material used, Delivery System and or Deployment Method, Physical Properties and Patient Population. The subject device also successfully passed all verification and validation testing, including the biocompatibility assessment.

In summary it can be stated that the development of the subject device, UltraCal XS, is based on a well-established technology in the form of the predicate device, DiaPaste (K210333) and is chemically equivalent to the previously submitted UltraCal XS (K970114). The decision to rely on DiaPaste (K210333) as the predicate rather than the previously submitted UltraCal XS (K970114) is due to the updated indications of the subject device. In order to establish substantial equivalence, DiaPaste (K210333) was selected as the best fit predicate based off of chemistry and cleared indications for use.

Based on the completed testing and the comparisons to the predicate device, we believe that UltraCal XS is substantially equivalent to the predicate device and does not raise any different questions regarding safety and effectiveness.